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TEST REPORT

Regulatory consultancy report: EU and FDA compliance of AGCCE/AGC manufactured grades

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Work reported in this document is outside the scope of the UKAS ISO 17025 accreditation for UKAS Laboratory No. 0967.

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Test Report

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1. Introduction

Description of Work

AGCCE Ltd ('the client') engaged the services of Intertek Wilton to perform Regulatory consultancy work. This was to assess the European (EU) and United States Food and Drugs Administration (US FDA) compliance of AGCCE/AGC European manufactured grades to the relevant food contact regulations.

The work was to be based on the findings of the work completed against W11413 which was a compositional assessment and review of Declarations of Compliance.

The deliverables for this stage were:

A written gap analysis covering the compositional compliance, cross referencing the current Food Contact statements, with AD and FL grades the priority. This was also to include reference to the further requirements for compliance with good manufacturing practice (GMP) 2023/2006 over and above ISO 9001 certification.

Updated and corrected wording for the current Food Contact statements, cross referenced with the recipe information provided. This will be with reference to the updated EC Guidance.

Review of current customer questionnaires and proposed strategy for answering, with wording provided where appropriate or testing required proposed.

Further advice, as required and directed by the client, on proposed testing strategies to fill any gaps discovered in background documentation for existing grades.

Regulatory Background

The Framework Regulation: Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food lays down common rules for packaging materials and articles, which come, or may come, into contact with food, either directly or indirectly.

It seeks to protect human health and consumers' interests as well as ensure that the products used may be sold anywhere in the European Economic Area

- The legislation identifies 17 groups of materials and articles, ranging from cork and glass to plastic and textiles, where specific measures may be adopted.
- For materials and articles covered by specific measures, a Declaration of Compliance shall accompany them; this must state that they comply with the rules applicable to them.
- The specific measures may include measures such as purity standards and a list of the substances used.
- An application for the use of a new substance must be submitted to the relevant national authority which then forwards it to the European Food Safety Authority for its opinion.
- Materials used for packaging must be identified as 'for food contact' and accompanied by a suitable logo.
- Traceability measures must be in place to make it possible to recall any defective products or provide the public with specific information.

Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food lays down the rules on GMP for materials and articles that come into contact with food.

The legislation applies to all sectors and all stages of manufacture, processing and distribution of materials and articles.
Businesses must:

- conform with good manufacturing practice; which is defined as those aspects of quality assurance that ensure materials and articles conform to quality standards, do not endanger human health or cause an unacceptable change in the composition of the food.
- establish, implement and apply an effective and documented quality assurance system; which is defined as an organised and documented arrangements that ensure materials and articles meet the quality required.
- establish and maintain an effective quality control system;
- establish and maintain appropriate records, either in paper or electronic form, on specifications, formulae and processing on the safety of the individual product and the various manufacturing operations.

Quality assurance systems take account of:

- the staff's knowledge and skills and the organisation of the premises and equipment;
- the size of the business to prevent them being an excessive burden.

Quality control systems include:

- monitoring the implementation of good manufacturing practice; and
- identifying and correcting any measures that fall short of the required standards.

With regard to the particular requirements of GMP over and above a typical quality management system such as ISO 9001, they are in the areas of contamination control, management of change and good housekeeping measures. The producer of the FCM must show that they have considered the areas of contamination control, management of change and good housekeeping measures with respect to Good Manufacturing Practice for the production of food contact materials. As there are no legal

guidelines for the establishment of GMP, producers are free to employ any method they choose as long as it is documented and can be produced for national competent authorities for inspection on demand.

The Plastics Implementation Measure (PIM): Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004 and establishes specific rules for plastic materials and articles.

The regulation introduces migration limits for substances used in such packaging and lays down conditions for their use to ensure food safety.

It sets out the requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food. These requirements supplement the general rules laid down in Regulation (EC) No 1935/2004 on materials and articles used for food packaging.

The plastic materials and articles and parts thereof may be composed:

- exclusively of plastics;
- of several layers of plastics; or
- of plastics combined with other materials.

The regulation lists the substances that may be intentionally used in the manufacture of plastic materials and articles. Including monomers, additives (excluding colorants); polymer production aids (excluding solvents); and macromolecules obtained from microbial fermentation.

New substances are added to the list if the European Food Safety Authority issues a favourable opinion following an application and approval procedure.

To be placed on the EU market, the plastic materials and articles in question must comply with:

- the requirements for use, labelling and traceability set out in Regulation (EC) No 1935/2004;
- the good manufacturing practice defined in Regulation (EC) No 2023/2006;
- requirements regarding composition and the declaration on compliance.

The Regulation's annexes set out the conditions of use for authorised substances and migration limits. All plastic materials and articles must comply with specific migration limits and overall migration limits.

The manufacturer must draw up a written declaration (Annex IV). This must identify the materials, articles and products from the intermediate stages of their manufacture, as well as the substances themselves. It must be renewed when substantial changes in the composition or production occur.

In the US, the overall regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. Any individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material shall be covered by one of the following:

- a regulation listed in Title 21 Code of Federal Regulations (21 CFR)
- meeting the criteria for GRAS status (including but not limited to a GRAS regulation or GRAS notice)
- a prior sanction letter
- a Threshold of Regulation (TOR) exemption request
- or an effective Food Contact Substance Notification (FCN).

It is the responsibility of the manufacturer to ensure that food contact materials comply with the specifications and limitations in all applicable authorisations. When reviewing formulations to determine compliance, each authorisation must be considered to be composed of three parts: the identity of the substance, specifications including purity or physical properties and limitations on the conditions of use.

For polymerised products such as those manufactured by the client, even though they may not strictly fall under the definition of a plastic layer as laid out in the PIM, the easiest way to show compliance with the Framework Regulation is to show compositional and potentially migration compliance with the PIM. For a Declaration of Compliance, the guidance to the Annex IV requirements in the PIM produced by the EC is a comprehensive document which details the adequate information which should be communicated in the supply chain. For the US FDA compliance, if a DoC is unavailable from a supplier, in the first instance the applicable chapter of the 21 CFR is consulted with regard to the type of polymer concerned to establish compliance before looking at other methods of compliance.

In summary, the aim of food contact material legislation the world over is to prevent adulteration of the food which contacts it. The route that business operators must follow is a risk assessment of the materials to show that they will not cause harm to human health, taking account of any local material specific legislation. In the case of both EU and US FDA compliance, the route is to review any supplier documentation and if necessary, the recipe of the material down to the CAS number of individual substances. The function of the substance in the final article must be considered, along with any specifications or restrictions; and these must be respected in the intended end use of the final article. The intended end use should be understood, but the amount of information required in any DoC depends on the position in the supply chain of the legal entity responsible for marketing the material. The final legal responsibility is always on the business operator who places the final FCM or article on the market at the point where it reaches the final user.

2. Documentation supplied

A large number of documents were supplied for review, based on the previous Regulatory compliance work carried out. These are available in the Intertek Wilton filing system along with this report. They included copies of the current food contact documentation and the recipes of the materials.

3. Recipe of the materials

The recipes of the following grades were supplied by the client:

Fluon ETFE grades
C55AP
C88AXM
C88AXM-HT

4. Compliance of the materials

Compositional compliance

A composition summary was provided by the client.
A compilation of the formulations was composed and used to consider the substance listings for both EU and FDA food contact applications:

ETFE GRADES

Chemical	CAS No	Function	FDA	EU
TFE	116-14-3	monomer	177:1550[8]	FCM281, SML 0.05mg/kg
Ethylene	74-85-1	monomer	177:1550[8]	FCM125, No Restriction
PFBE	19430-93-4	monomer	FCN 1723[14] check relevance of listing	FCM973, Restriction 0.01% addition
Methanol	67-56-1	chain transfer agent	Listed, but not for application, not required to be as an AP, must comply with GMP.[11]	FCM117, No Restriction
Alumina	1344-28-1	thermal stabiliser[6]	TOR No. 2005-001[6] AGC Japan allows up to 500 ppm in ETFE polymer	FCM418, No Restriction
Trigonox 25-C75	927-07-1	Used as a polymerization initiator[3]	FDA No Objection Letters for its use as a catalyst, initiator and suspension agent[4]	Resolution AP (92)2 Aids to Polymerisation Table 2.2 (as a peroxide) SML 0.05mg/kg[7]
Nitrogen	7727-37-9	provide safe atmosphere for the reaction	GRAS 184:1540[19] and 177:1550[8] (as GRAS)	Exempt under 1935/2004
Potassium Nitrate	7757-79-1	processing aid, potassium nitrate consumed	21 CFR 170.39[20] Exempt	Dutch Warenwet Ch X para 3.m no restriction AP (92)2 Aids to polymerisation as potassium compounds SML = 60 mg/kg
SAA -1000	908020-52-0	polymerisation aid	Not listed, not required to be as an AP, must comply with GMP.[11]	FCM926, Restriction "Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes".
C6H	355-37-3	solvent	FDA generally do not regulate solvents	Solvent, not required to be listed
MSP	68258-85-5/ 1317-38-0	CuO as Aid to Polymerisation/ Additive	FCS No 481 used as a base resin or coating in repeat-use applications – NOT APPLICABLE, current submission underway	MSP is Polymer Not listed/ CuO AP (92) 2, SML 30mg/kg 10/2011 Annex II SML = 5 mg/kg as copper MSP Listed monomers: FCM 973*"Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures."* FCM281, SML 0.05mg/kg FCM 125, no restriction

Notes on compliance:

3. PubChem https://pubchem.ncbi.nlm.nih.gov/compound/61238 accessed 20th March 2020

6. TOR notice https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=TOR&id=200^{5}-001
7. "** No peroxide compounds should be extracted from the final article after immersion in distilled water for 24 hours at 23ºC ± 3º C, using an analytical method with a limit of detection of 0,05 mg/kg of active oxygen. Where no volume to surface area ratio is specified, the test should be at the ratio of 1 dm2 to 6 dm2 of surface area. For H2O2 the maximum permitted migration is 0,5 mg/kg as active oxygen."
8. PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces Sec. 177.1550 Perfluorocarbon resins. (a) (1) "The homopolymerization…of…tetrafluoroethylene"

11. Basic polymer doctrine. Not specifically stated in US legislation but elaborated in numerous papers and by FDA policy. States that catalysts, chain transfer agents, reaction control agents and other substances need to be integral to the polymerization process, used in small quantities, washed out or become a part of the polymer backbone, and not affect the suitable purity of the polymer. Controls are due diligence and GMP.

14. US FDA Inventory of Effective Food Contact Substance (FCS) Notifications FCN No. 1723 AGC Chemicals Europe "1-hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-, polymer with 1,1,2,2-tetrafluoroethene (CAS Reg. No. 82606-24-4). Intended use: As a base resin or coating in repeat-use applications. Limitations/Specifications: For use with all food types without temperature limitation."
https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1723&sort=FCN_No&order=DESC&startrow=1&type=basic&search=1723

19. PART 184 -- DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE Subpart B--Listing of Specific Substances Affirmed as GRAS Sec. 184.1540 Nitrogen https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1540
20. PART 170 -- FOOD ADDITIVES Subpart B--Food Additive Safety Sec. 170.39 Threshold of regulation for substances used in food-contact articles. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=170.39

5. Conclusion

ETFE grades containing PFBE are not compliant with US FDA requirements unless those grades can be shown to be compliant with FCN 1723.

6. Further work recommendations

7. References

Framework Regulation: Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, as amended

Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, as amended

Plastics Implementation Measure (PIM): Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended

EC Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain

Commercial Regulatory Databases (Ariel WebInsight and Decernis)

Customer information

8. Disclaimer

The information contained in this document is given in good faith and is based on the information received, to the best of our knowledge it is accurate as of the date published. Any changes to regulations, chemical formulation of the product or usage will render this document null and void

Abbreviations
EC European Commission
FCM food contact material
FCS food contact substance
CMR - carcinogenic, mutgenic or reprotoxic
CoRAP - Community Rolling Action Plan
10/2011 - Plastics Implementation Measure (PIM): Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended up to Commission Regulation (EU) No 2019/1338
GRAS – Direct Food Substances Affirmed As Generally Recognised As Safe, as defined in US FDA 21 CFR 184.1 and subsequent parts
GMP – Good Manufacturing Practice

Report authorisation

[redacted]

Date: 22/06/2020

[redacted]

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